K140158

MAY 2 9 2014

510(k) Summary
for the S.E.A.L. Fracture Fusion Tube

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the S.E.A.L. Fracture Fusion Tube.

1. GENERAL INFORMATION

Date Prepared: January 15, 2014

Trade Name: S.E.A.L. Fracture Fusion Tube

Common Name: External Fixation Frame

Classification Name: Single/multiple component metallic bone fixation appliances and accessories.

Class: II

Product Code: KTT

CFR section: 21 CFR section 888.3030

Device panel: Orthopedic

Legally Marketed Predicate Devices:
SBi Mini Rail External Fixation System (Small Bone Innovations, Inc., K093550)
Vilex Rail Fixation System (Vilex eX-Fix, K052196)
DFS ® MiniFixator (EBI (Biomet), K951357/K970290)
Tomahawk Mini Fixator (Wright Medical, K052005)

Submitter: DNE, LLC
2225 Park Place
Slatington, PA 18080
(610)-442-1017

Contact: J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199 Tele
512-692-3699 Fax
e-mail: jdwebb@orthomedix.net

2. DEVICE DESCRIPTION

The S.E.A.L. Fracture Fusion Tube provides a solution for fractures and for lengthening of small bones. The system allows controlled compression / distraction and early weight bearing. The articulating pin clamps allow adjustment around three axes and linear translation so that it can be used for comminuted intra-articular fractures or arthrodesis of the foot or hand. The fixator design enables pins to be located in multi-planar arrangements, allowing the frame to be built around the fractures in the hand or foot.

Materials:

6061-T6 Aluminum
316L Stainless steel
PTFE
PEEK

Function:

The S.E.A.L. Fracture Fusion Tube is indicated for stabilizing various fractures including open and/or comminuted fractures, fractures with length discrepancies, fusions and corrective osteotomies of the metacarpal and metatarsal bones

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The S.E.A.L. Fracture Fusion Tube is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

The S.E.A.L. Fracture Fusion Tube is indicated for use in external fixation of fractures and/or reconstruction of small bones, including metacarpal and metatarsal.

5. NON-CLINICAL TEST SUMMARY

Testing was performed following ASTM F1541-02 Annex 7.

The results of this analysis indicate that the S.E.A.L. Fracture Fusion Tube is equivalent to predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

D.N.E considers the S.E.A.L. Fracture Fusion Tube to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2014

DNE, LLC
% J.D. Webb
The OrthoMedix Group, Incorporated
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K140158
Trade/Device Name: S.E.A.L. Fracture Fusion Tube
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: April 17, 2014
Received: April 21, 2014

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K140158

Device Name

S.E.A.L. Fracture Fusion Tube

Indications for Use *(Describe)*

The S.E.A.L. Fracture Fusion Tube is indicated for use in external fixation of fractures and/or reconstruction of small bones, including metacarpal and metatarsal.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices